

## EVALUATION OF THE EFFECT OF RITUCHARYA ON SPIROMETRIC PARAMETERS IN PATIENTS OF BRONCHIAL ASTHMA

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### ABSTRACT

Human beings and environment are the two faces of a same coin, which are much complex, dynamic, inter-dependent, mutually reactive and inter-related. Annual change of seasons leads to disturbance in the equilibrium of Tridosha in the body. Non-observance of Ritucharya (specific regimen of six different seasons) leads to further imbalance of doshas and various diseases, Bronchial asthma (Tamaka Shvasa) is an important one of them. Asthma is thought to be caused by a combination of genetic and environmental factors. It is estimated to cause between 3,500 and 5,000 deaths annually in the United States.

Global burden of Asthma could be reduced by combined efforts of patients and their health care providers in terms of awareness and observance of Ritucharya along with standard drug therapy. This clinical study was done to evaluate the effect of observance of Ritucharya on Spirometric parameters of Bronchial Asthma (Tamaka Shvasa) patients, especially Forced Expiratory Volume in one second and Forced Vital Capacity. Out of total 140 patients, group A cases were advised to take modern standard drug therapy and group B cases were advised to follow particular Ritucharya in different seasons along with standard drug therapy. Changes in different parameters were recorded at three follow-ups. There was statistically significant increase in FEV<sub>1</sub> and FVC values of group B cases as compared to cases of group A. These findings show the additive effect of the observance of Ritucharya for improvement of lung functions and better management of Bronchial Asthma.

**KEYWORDS:** FEV<sub>1</sub>, FVC, Ritucharya, Tamaka Shvasa

### INTRODUCTION

Bronchial Asthma is an episodic disease of airway inflammation, with acute exacerbation interspersed with symptoms free period. It is manifested physiologically by a widespread narrowing of air passages, and clinically by paroxysms of dyspnoea, cough and wheezing. The obstruction within the lungs is often reversible either spontaneously or with treatment<sup>1</sup>. Total prevalence of Asthma estimated to be 7.2% of the world population, 6% in adults and 10% in children. It is increasing day by day with increase in the level of pollution and stressful lifestyle of people.

According to Global Initiative for Asthma (GINA) report, the rate of Asthma increases as communities adopt western lifestyle and become urbanized. The burden of Asthma is experienced not only in terms of healthcare costs but also as lost productivity and reduced participation in family life.

Factors influencing the risk of Asthma can be divided into those that cause the development of Asthma and those that trigger Asthma symptoms; some do both. The former include host factors which are primarily genetic and the latter are usually environmental factors.

Seasonal asthma can be triggered with the change of weather and by any airborne allergens. Trees, grasses or flowers are suspects because they release pollen in the air on a regular basis. The symptoms in spring are triggered by high levels of pollens, and in the fall are usually set off by ragweed<sup>2</sup>. Peanuts and shellfish, cold, damp, windy, stormy weather, sudden or extreme temperature changes, high humidity and smog are common Asthma triggers related to food and weather<sup>3</sup>. Food containing Sulfites may cause breathing difficulty within minutes after eating. The incidence of Sulfite sensitivity in the general population is thought to be less than 2%, but this rises to between 5 and 13% in Asthmatics. Sulfites work as food preservatives by releasing sulphur dioxide. This is an irritant gas, can cause the airway to become irritated and constricted<sup>4</sup>.

Tamaka Shvasa has been described in Ayurvedic texts as a type of Shvasa roga, which is clinically similar to Bronchial Asthma. In Tamaka Shvasa patient feels darkness or suffocation or choking during respiration with extreme weakness, fatigue and mental glooming. It is mainly a Kaphaja-Vataja disorder with Kapha as a leading Dosha. Vata moving in the reverse order pervades the channels afflicts the neck and head, and stimulate kapha to cause rhinitis and obstruction of the passage of pranavayu which then get vitiated and produces Ghurghuraka shabda (wheezing), Kasa (cough), Pramoha (faintness), Anidra (disturbed sleep) etc. Patient gets frequent paroxysms of dyspnoea, feels excessive restlessness, and gets relief for a while after spitting the sputum. The attacks get aggravated by cloudy, humid, and cold weather, easterly wind and with the use of Kapha aggravating food and regimen<sup>5</sup>.

Human beings are directly affected by seasonal variations, leading to disturbance in equilibrium of Tridosha in the body. Observance of specific Ritucharya (regimen of six different seasons) maintains the balance of doshas and makes the person free from seasonal diseases<sup>6</sup>.

The prevalence of diseases like Tamaka Shvasa, Amlapitta, Pratishyaya, Shirahshoola, Kushtha etc. increases due to non-observance of Ritucharya. The major risk factors for Tamaka Shvasa are exposure to cold air, rain and cloudy sky, exposure to dust, exposure to smoke, fog, living in humid environment, sedentary lifestyle, day time sleeping, intake of cold items, curd, buffalo's milk and its products, rice and fruits at night<sup>7</sup>. Majority of the modern medicines employed for treatment of Bronchial Asthma are limited to suppress the symptoms only.

A repeated and long term use of such drugs has been found to cause serious side effects also. By the only use of medicines, it may not be possible to prevent and control this disease. Hence this is the right time to project the concept of Ritucharya in terms of self-management, along with setting goals for treatment. Sometimes, healthy regimen in itself is a complete treatment. It is said that if a patient follows the pathya, there is no need of medicine, because the patient will be cured by pathya only or medicines would be more effective. On the other hand, if the patient does not follow the pathya, there is no need of medicine, as the medicine proves futile alone without taking pathya<sup>8</sup>.

## Spirometry

Spirometry is the common method of measuring lung function, specifically the amount (volume) and/or speed (flow) of air that can be inhaled and exhaled. Spirometry is useful to diagnose or manage asthma<sup>9</sup>, to diagnose and differentiate between obstructive and restrictive lung disease and to follow the natural history of disease in respiratory conditions<sup>10</sup>. The most common parameters measured in Spirometry are Vital capacity (VC), Forced Vital Capacity (FVC), Forced Expiratory Volume (FEV) at timed intervals of 0.5, 1.0 (FEV<sub>1</sub>), 2.0, and 3.0 seconds, forced expiratory flow 25–75% (FEF 25–75) and maximal voluntary ventilation (MVV)<sup>11</sup>.

In Asthma a decrease in the absolute value and percent predicted of forced expiratory volume in 1 second (FEV<sub>1</sub>) to less than 80% of predicted normal may be present. In addition to FEV<sub>1</sub> the ratio of FEV<sub>1</sub> to FVC ratio is often below 70%. Average values for FEV<sub>1</sub> in healthy people depend mainly on sex and age, of between 80% and 120% of the average value are considered normal<sup>12</sup>.

FEV<sub>1</sub>/FVC (FEV<sub>1</sub>%) is the ratio of FEV<sub>1</sub> to FVC. In healthy adults this should be approximately 75–80%. In obstructive diseases like asthma, chronic bronchitis and emphysema FEV<sub>1</sub> is diminished because of increased airway resistance to expiratory flow; the FVC may be decreased as well, due to the premature closure of airway in expiration, just not in the same proportion as FEV<sub>1</sub>. Here FEV<sub>1</sub> and FVC both are reduced, but the former is more affected because of the increased airway resistance.

## OBJECTIVE OF CLINICAL STUDY

To evaluate the effect of Ritucharya (Seasonal Regimen) on FEV<sub>1</sub> (Forced expiratory volume in one second) and FVC (Forced vital capacity) in the patients of Bronchial Asthma (Tamaka Shvasa)

## MATERIALS AND METHODS

This study was done in the OPD of T.B. and Respiratory Diseases, Sir Sundar Lal Hospital, Institute of Medical Sciences, Banaras Hindu University, Varanasi, from July 2009 to July 2012. Total 140 well diagnosed patients of Bronchial Asthma with different age group, gender, occupation, socio-economic status, prakriti, were randomly selected on the basis of following criteria:

### Inclusion Criteria

- Age 16 - 60 yrs
- Patients of Bronchial Asthma (Tamaka Shvasa) fulfilling the diagnostic criteria of modern and Ayurvedic medicine

### Exclusion Criteria

- Age <16 yrs and >60 yrs
- Patients of Pratamaka and Santamaka Shvasa
- Patients of Status Asthmaticus, Chronic Obstructive Pulmonary Disease, Bronchiectasis, Pneumothorax, Eosinophilia, Pulmonary Oedema, Cor-pulmonale, Pulmonary Tuberculosis or any other chronic lung disease

- Patients of Hypertension, Ischemic Heart Disease, Cardiac Arrhythmia, Valvular Heart Disease, Patients of Fever, Migraine, Diabetes Mellitus or any other chronic disease

### Study Design

All registered patients of Bronchial Asthma were randomly allocated into two groups of 70 cases each:

**Group A:** Control group (Taken Standard drug therapy)

**Group B:** Trial group (Followed particular Ritucharya along with Standard drug therapy)

Patients of group A had taken modern Standard drugs including Budamate 400 inhaler, two puffs twice a day (Budesonide 400 microgram + Formoterol 6 microgram per puff) along with Tab.

Deriphyllin Retard (150 mg), twice in a day, for initial one month; followed by Budamate inhaler only, during rest period of study. Patients of group B were advised to follow the particular regimen during six seasons along with Standard drug therapy as advised to group A cases. Changes in clinical parameters were observed at three follow-ups at an interval of one, two and two months, for a total period of five months. Out of 140 registered cases, 8 patients of group A and 10 patients of group B dropped out before the completion of study.

### Evaluation Criteria

All selected patients were subjected to demographic profile, clinical profile, and detailed history about dietary habits and lifestyle predominantly followed during six different seasons of a year. Clinical assessment of symptoms and severity was done on the basis of Subjective and Objective criteria at the time of registration and subsequent 3 follow-ups. Forced vital capacity (FVC) is the total volume of air in liters exhaled during forced and maximum exhalation after maximum inhalation. Forced expiratory volume in one second (FEV<sub>1</sub>) is the volume of air in liters exhaled during first one second in forced expiration after forced inspiration. FVC and FEV<sub>1</sub> were recorded with computerized Spirometer. SPSS Software version 16.0 was used to apply the statistical methods for analysis of data and finding of results.

### OBSERVATIONS AND RESULTS

In this study group of 140 patients of Bronchial Asthma, 69.3% were in the age group ranging between 15-44 years, 57.1% were males, 92.9% were Hindu, 74.3% were educated, 70.0% belonged to urban community, and 60.7% were of middle socioeconomic group. Maximum registered cases 84(60.0%) had negative family history of the disease, and 98 (70.0%) were suffering from Bronchial Asthma for less than 5 years. The clinical observations based on subjective and objective parameters were statistically analyzed and summarized.

Significant improvement in clinical features and FEV<sub>1</sub> and FVC values was observed. On intergroup comparison the patients of group B showed significant improvement in many symptoms like Dyspnoea, Wheezing, Cough, Rhinorrhoea, Frequency of attack and Duration of attack. In case of Expectoration, Orthopnoea, Soreness of Throat, Heaviness of Head, and Chest pain statistically not significant difference was observed between the two groups, however clinically more significant results were obtained in patients of group B as compared to group A patients<sup>13</sup>. More significant increase in the values of Peak Expiratory Flow Rate (PEFR) was also observed in group B cases<sup>14</sup>.

**Table 1: Effect on Ritucharya on Forced Vital Capacity (FVC)**

Group	FVC Score Mean $\pm$ SD				Within the Group Comparison (Paired t Test)		
	BT	F1	F2	F3	BT – F <sub>1</sub>	BT – F <sub>2</sub>	BT – F <sub>3</sub>
<b>Group-A</b>	1.56 $\pm$ 0.46	1.84 $\pm$ 0.46	2.10 $\pm$ 0.39	2.30 $\pm$ 0.46	0.29 $\pm$ 0.29 t = 8.07 p<0.001	0.57 $\pm$ 0.32 t = 14.48 p<0.001	0.78 $\pm$ 0.42 t = 14.65 p<0.001
<b>Group-B</b>	1.65 $\pm$ 0.56	2.04 $\pm$ 0.63	2.38 $\pm$ 0.49	2.68 $\pm$ 0.45	0.39 $\pm$ 0.30 t = 10.51 p<0.001	0.73 $\pm$ 0.32 t = 18.31 p<0.001	0.99 $\pm$ 0.40 t = 19.07 p<0.001
<b>Between the Groups Comparison (Unpaired t Test)</b>	t = 1.15 p>0.05	T = 2.09 p<0.05	t = 3.56 p<0.01	t = 4.51 p<0.001			

In group A mean  $\pm$  SD of forced vital capacity at the time of registration was 1.56  $\pm$  0.46, which was increased to 2.30  $\pm$  0.46 after complete follow up. These results were statistically highly significant (t = 14.65, p<0.001). In group B the mean score was increased from 1.65  $\pm$  0.56 to 2.60  $\pm$  0.45 at third follow-up, showing statistically highly significant results (t = 19.07, p<0.001). During inter-groups comparison by Unpaired t test it can be concluded that at first follow-up results were statistically significant (p<0.05), however at second and third follow ups highly significant p values were obtained.

**Table 2: Effect of Ritucharya on Forced Expiratory Volume in One Second (FEV<sub>1</sub>)**

Group	FEV <sub>1</sub> Score Mean $\pm$ SD				Within the Group Comparison (Paired t Test)		
	BT	FU <sub>1</sub>	FU <sub>2</sub>	FU <sub>3</sub>	BT-FU <sub>1</sub>	BT-FU <sub>2</sub>	BT-FU <sub>3</sub>
<b>Group-A</b>	1.26 $\pm$ 0.41	1.51 $\pm$ 0.35	1.70 $\pm$ 0.32	1.87 $\pm$ 0.43	0.25 $\pm$ 0.27 t = 7.58 p<0.001	0.46 $\pm$ 0.33 t = 11.18 p<0.001	0.63 $\pm$ 0.48 t = 10.29 p<0.001
<b>Group-B</b>	1.30 $\pm$ 0.48	1.68 $\pm$ 0.48	1.95 $\pm$ 0.41	2.27 $\pm$ 0.39	0.37 $\pm$ 0.29 t = 10.42 p<0.001	0.62 $\pm$ 0.32 t = 15.44 p<0.001	0.94 $\pm$ 0.39 t = 18.90 p<0.001
<b>Between the Groups Comparison (Unpaired t Test)</b>	t = 0.58 p>0.05	t = 2.38 p<0.05	t = 3.86 p<0.001	t = 5.47 p<0.001			

In group A the mean  $\pm$  SD of Forced Expiratory Volume in one second at the time of registration was 1.26  $\pm$  0.41, which was increased to 1.87  $\pm$  0.43 after complete follow up. These results were statistically highly significant (t = 10.29, p<0.001). In group B the mean score was increased from 1.30  $\pm$  0.48 to 2.27  $\pm$  0.39 at third follow up, showing statistically highly significant result (t = 18.90, p<0.001). During inter-groups comparison by Unpaired t test it was observed that at first follow up the results were statistically significant (p<0.05) where as at second and third follow ups p values were highly significant (p<0.001).

## DISCUSSIONS

If a man knows the suitable regimen for every season and practices accordingly his strength and luster enhance and he never suffers from diseases due to the aggravated doshas under the seasonal impact. On the basis of history about diet and behaviour observed during different ritus it was found that maximum patients were aware about six seasons and regimen of different seasons but about half of the cases were observing Ritucharya occasionally and less number of cases

were found to adhere with Ritucharya regularly. Out of 140 patients of Tamaka Shvasa maximum number of patients attended the hospital first time in Hemanta and Shishira (winter seasons), Vasanta (spring) and Varsha (rainy season), and in majority of cases these were the predominant seasons of Asthma attack. It indicates the increased prevalence of Asthma in winters, spring and rainy season.

About two third cases were adhered with the habit of bathing with cold water in winters. Maximum number of cases preferred shita, guru, madhura and amla rasa predominant ahara like ice-cream, cold drink, fruit juices, cold water, sweets, curd, rice, pickle, tomato ketchup, salad with lemon in all seasons., These food items are Kapha and Vata vitiating, which can trigger the attack of Asthma. Foods containing Sulfites like ice-cream, cold drink, fruit juices, pickle, tomato ketchup, etc can precipitate breathing problem. So these food items should be contraindicated. Day time sleeping (Divasvapna) has been advocated only in Grishma season and during rest of the five seasons is contraindicated as it increases the Kapha. The living place should be non-humid in Varsha season and hot and dry in Shishira and Hemanta seasons.

In both groups A and B significant improvement was observed in clinical symptoms, like Dyspnoea, Wheezing, Cough, Rhinorrhoea, Frequency of attack and Duration of attack. In case of computerized Spirometry, at each follow up the mean values of FVC and FEV<sub>1</sub> were significantly increased in both groups A and B, showing efficiency of both interventions. On inter group comparison by Unpaired t test it can be concluded that at first follow-up the results of FVC and FEV<sub>1</sub> were statistically significant, however at second and third follow ups highly significant p values were obtained. These findings depict the additive effect of the observance of Ritucharya (along with standard drug therapy) to improve the lung functions of Bronchial Asthma patients.

## CONCLUSIONS

In this modern era the prevalence of Bronchial Asthma is increasing and its management through conventional system of medicine is still challenging. The awareness of individuals towards healthy seasonal regimen is essential, along with the family, community and whole nation participation for prevention and control of this episodic disease. Present study reveals that regular observance of Ritucharya has direct influence on clinical features and lung functions in the patients of Bronchial Asthma. FVC and FEV<sub>1</sub> values are useful to diagnose Asthma, and to follow the lung functions and disease severity. These values were increased significantly in the patient of group B who followed the strict seasonal regimen along with standard drug therapy. The cost effective non-pharmacological approach of Ritucharya should be incorporated in future health strategies to reduce the global burden of Bronchial Asthma.

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